(iv) For each sampler and for each of the 3 test days on which flow measurements were obtained at 6-hour intervals throughout the 24-hour sampling period, calculate and record the percent differences between each measured flow rate and the initial flow rate as:

$$\Delta F_{(i)(j)(t)} = \frac{F_{(i)(j)} - F_{(i)(j)(0)}}{F_{(i)(j)(0)}} \times 100\%$$

where t = 6, 12, 18, or 24 hours.

(v) The candidate method passes the flow rate stability test if all of the $\Delta F_{(i)(j)}$ and $\Delta F_{(i)(j)(t)}$ values meet the specifications in table D–1.

Subpart E—Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I Equivalent Methods for $PM_{2.5}$

SOURCE: 62 FR 38799, July 18, 1997, unless otherwise noted.

§ 53.50 General provisions.

(a) This subpart sets forth the specific tests that must be carried out and the test results, evidence, documentation, and other materials that must be provided to EPA to demonstrate that a $PM_{2.5}$ sampler associated with a candidate reference method or Class I equivalent method meets all design and performance specifications set forth in 40 CFR part 50, appendix L, as well as additional requirements specified in this subpart E. Some of these tests may also be applicable to portions of a candidate Class II equivalent method sampler, as determined under subpart F of this part. Some or all of these tests may also be applicable to a candidate Class III equivalent method sampler, as may be determined under § 53.3(a)(4) or § 53.3(b)(3).

(b) Samplers associated with candidate reference methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in §§ 53.51 through 53.58. Samplers associated with candidate Class I equivalent methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all sections of this subpart. Samplers associated with candidate Class II equivalent methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all applicable sections of this subpart, as specified in subpart F of this part.

(c) The provisions of § 53.51 pertain to test results and documentation required to demonstrate compliance of a candidate method sampler with the design specifications set forth in 40 CFR part 50, appendix L. The test procedures prescribed in §§ 53.52 through 53.59 pertain to performance tests required to demonstrate compliance of a candidate method sampler with the performance specifications set forth in 40 CFR part 50, appendix L, as well as additional requirements specified in this subpart E. These latter test procedures shall be used to test the performance of candidate samplers against the performance specifications and requirements specified in each procedure and summarized in table E–1 of this subpart.

(d) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I equivalent method samplers for $PM_{2.5}$ which have a sample air flow path configuration upstream of the sample filter that is modified with respect to that specified for the reference method sampler, as set forth in 40 CFR part 50, appendix L, figures L–1 to L–29, such as might be necessary to provide for sequential sample capability. The additional tests determine the adequacy of aerosol transport through any altered components or supplemental devices that are used in a candidate sampler upstream of the sample filter. In addition to the other test procedures in this subpart, these test procedures shall be used to further test the performance of such an equivalent method sampler against the performance specifications given in the procedure and summarized in table E–1 of this subpart.

(e) A 10–day operational field test of measurement precision is required under § 53.58 for both candidate reference and equivalent method samplers. This test requires collocated operation of three candidate method samplers at a field test site. For candidate

equivalent method samplers, this test may be combined and carried out concurrently with the test for comparability to the reference method specified under § 53.34, which requires collocated operation of three reference method samplers and three candidate equivalent method samplers.

(f) All tests and collection of test data shall be performed in accordance with the requirements of reference 1, section 4.10.5 (ISO 9001) and reference 2, part B, section 3.3.1, paragraphs 1 and 2 and part C, section 4.6 (ANSI/ASQC E4) in appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

(a) *Overview.* (1) The subsequent paragraphs of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated reference or equivalent method for $PM_{2.5}$ are properly manufactured to meet all applicable design and performance specifications and have been properly tested according to all applicable test requirements for such designation. Documentation is required to show that instruments and components of a $PM_{2.5}$ sampler are manufactured in an ISO 9001-registered facility under a quality system that meets ISO-9001 requirements for manufacturing quality control and testing.

(2) In addition, specific tests are required to verify that two critical features of reference method samplers impactor jet diameter and the surface finish of surfaces specified to be anodized meet the specifications of 40 CFR part 50, appendix L. A checklist is required to provide certification by an ISO-certified auditor that all performance and other required tests have been properly and appropriately conducted, based on a reasonable and appropriate sample of the actual operations or their documented records. Following designation of the method, another checklist is required, initially and annually, to provide an ISO-certified auditor's certification that the sampler manufacturing process is being implemented under an adequate and appropriate quality system.

(3) For the purposes of this section, the definitions of ISO 9001-registered facility and ISO-certified auditor are found in § 53.1. An exception to the reliance by EPA on ISO-certified auditors is the requirement for the submission of the operation or instruction manual associated with the candidate method to EPA as part of the application. This manual is required under § 53.4(b)(3). EPA has determined that acceptable technical judgment for review of this manual may not be assured by ISO-certified auditors, and approval of this manual will therefore be performed by EPA.

(b) *ISO registration of manufacturing facility.* (1) The applicant must submit documentation verifying that the samplers identified and sold as part of a designated $PM_{2.5}$ reference or equivalent method will be manufactured in an ISO 9001-registered facility and that the manufacturing facility is maintained in compliance with all applicable ISO 9001 requirements (reference 1 in appendix A of this subpart). The documentation shall indicate the date of the original ISO 9001 registration for the facility and shall include a copy of the most recent certification of continued ISO 9001 facility registration. If the manufacturer does not wish to initiate or complete ISO 9001 registration for the manufacturing facility, documentation must be included in the application to EPA describing an alternative method to demonstrate that the facility meets the same general requirements as required for registration to ISO-9001. In this case, the applicant must provide documentation in the application to demonstrate, by required ISO-certified auditor's inspections, that a quality system is in place which is adequate to document and monitor that the sampler system components and final assembled samplers all conform to the design, performance and other requirements specified in this part and in 40 CFR part 50, appendix L.

(2) Phase-in period. For a period of 1 year following the effective date of this